United States Court of Appeals

for the Second Circuit

APPELLANT'S BRIEF

76-1398

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United States Court of Appeals

FOR THE SECOND CIRCUIT

Docket No. 76-1398

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

—*against*—

DIAPULSE CORPORATION OF AMERICA, also known as THE DIAPULSE MANUFACTURING CORPORATION OF AMERICA, a corporation, JESSE ROSS, President of the corporation and JOSEPH I. ROSS, Vice-President and Treasurer of the corporation,
Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

DEFENDANTS-APPELLANTS' BRIEF

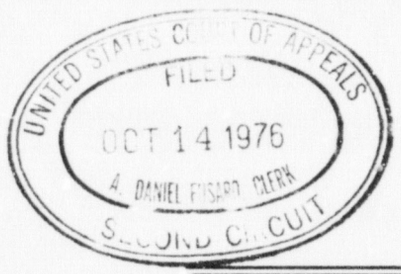

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TABLE OF CONTENTS

DEFENDANTS-APPELLANTS' BRIEF

CITATIONS

STATUTES

To be argued by
Copal Mintz

No. T-6444

UNITED STATES COURT OF APPEALS

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Plaintiff-Appellee,

-against-

DIAPULSE CORPORATION OF AMERICA, also known as THE DIAPULSE MANUFACTURING CORPORATION OF AMERICA, a corporation, JESSE ROSS, President of the Corporation, and JOSEPH I. ROSS, Vice-President and Treasurer of the Corporation,

Defendants-Appellants.

On Appeal from the United States District Court for the Eastern District of New York.

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DEFENDANTS' - APPELLANTS' BRIEF

Each of the above named defendants appeals from judgments of the United States District Court for the Eastern District of New York (John F. Dooling, Jr., D.J.) convicting them, after a jury trial, of Criminal Contempt, in October 1975, of a Permanent Injunction of that court dated July 18, 1974.

THE ISSUES

The appeals present the following questions:

1. Did the allegations of the petition (3-8)[1] as amplified by bills of particulars (9-14, 25-38), set forth facts sufficient to constitute a criminal contempt of court?

2. Did the evidence at the trial establish: (a) the charged criminal contempt, (b) beyond a reasonable doubt?

3. Did the trial court admit, over appellants' objections and exceptions, prejudicial inadmissible evidence?

4. If defendants have been properly convicted, are the fines (aggregating $6,250) excessive?

THE ESSENTIAL FACTS

The Record in this case[2] and the points which are raised in this appeal are such that it seems to appellants' counsel that the cause of conciseness as well as clarity will be served best by a detailed recital at the outset of this brief of the substance of the proceedings and the fraction of the 174 pages of testimony that need to be considered.

The Charged Contempts and Motions in Respect Thereto.

(1). The Government's petition (3-7) charged that on

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1. Except where otherwise indicated, numerals in parentheses refer to page numbers of the Appendix.

2. Unfortunately, the trial transcript is replete with errors and garbling.

two occasions -- July 2, 1975 and October 7, 1975 -- defendants Diapulse Corporation of America (hereinafter referred to as Diapulse) and its Vice-President-Treasurer Joseph I. Ross, and on October 15, 1975 those two and Diapulse's President Jesse Ross wilfully and knowingly violated the following provision of Section V(B) of the July 18, 1974 Permanent Injunction:

> "The defendant, Diapulse Corporation of America, a corporation shall:
>
> .....
>
> (B) Grant duly authorized officers and employees of the Food and Drug Administration free access to any of its offices, plants, factories, warehouses, storage facilities, or other establishments at reasonable times during regular working hours, within reasonable limits and in a reasonable manner to inspect such establishment and all pertinent equipment, finished and unfinished materials, containers, and labeling therein; and such inspection may include copying and photographing and shall also extend to all things therein (including records, files, papers, processes and facilities) bearing on whether any prohibited devices have been or are being manufactured, assembled, processed, packed, transported, or held in such place." (3)

That provision, the petition alleged, was violated by refusing to:

> "grant duly authorized employees of the Food and Drug Administration access to their establishment to inspect the establishment and all pertinent equipment, finished and unfinished materials, containers and labeling therein and to all things therein bearing on whether any pro-

hibited devices"

as defined in Section II(E) of said order of Permanent Injunction

> "have been or are being manufactured, assembled, processed, packed, transported or held in the establishment..."(6)

(2). In a Bill of Particulars (furnished pursuant to motion) the Government stated (9-10) that it relied on: 18 U.S.C. 401; Rule 42(b) of the Federal Rules of Criminal Procedure; Federal Food, Drug and Cosmetic Act, 21 U.S.C. 374(a) insofar as that section authorized the Secretary of Health, Education and Welfare to designate agents to make inspections and to conduct investigations; and on an alleged delegation by the Secretary and a chain of successive redelegations which resulted in the issuance to Food and Drug Investigators "FD Form 200 A, entitled 'Identification Record' ...and FD Form 200C, entitled 'Specifications of General and Special Authority' " which, on the occasions mentioned above, "were exhibited" by the investigators (27-8). Those two forms were received in evidence at the trial as Defendants' Exhibits A and D. Nothing else was exhibited.

"FD Form 200A" certified that the person named and described therein bore the signature of the authorized bearer.

"FD Form 200C" read as follows:

"DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
PUBLIC HEALTH SERVICE

This certifies that

(the person named therein)

whose photograph appears below is a duly accredited scientifically trained agent specifically authorized to have access to and copy or verify any records and reports required under Section 505(i) or (j) or 507(d) or (g) of the Federal Food, Drug and Cosmetics Act as amended and is authorized to administer oaths and affirmations and to act for the Commissioner in the performance of the duties provided in the laws and Department Regulations administered by the
FOOD AND DRUG ADMINISTRATION
No_____Expires_____ A.N.SCHMIDT
Commissioner of Food and Drugs"

The Bill of Particulars alleged further:

"...at the time of each attempted inspection ...a document entitled 'Notice of Inspection' was presented."

Copies of those notices were included in the Bill of Particulars (10, 12-14).

Those "Notice[s] of Inspection" (printed forms which are reproduced at 12-14) were addressed respectively to "Mr. Joseph I. Ross, Vice-Pres.-Treasurer of Diapulse Corporation of America" and to "Mr. Jesse Ross, President of Diapulse Corporation of America". They contained the signatures of the persons presenting them and their titles as "Food and Drug Administration employees". In pertinent parts they read as follows (with the blanks filled in):[3]

[3] Those Notices subsequently were received at the trial as Defendants' Exhibits B and B-1.

"DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS

2. NAME AND TITLE OF INDIVIDUAL

3. DATE

4. FIRM NAME

5. HOURS A.M. P.M.

6. NUMBER AND STREET

7. CITY AND STATE

8. ZIP CODE

Notice of inspection is hereby given pursuant to Section 704(a) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 USC 262-264].[2]

9. SIGNATURE (Food and Drug Administration Employee(s)

10. TITLE (Food and Drug Administration Employee(s)

[1]Applicable portions of Section 704 of the Federal Food, Drug and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704.(a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge are authorized (1) to enter, at reasonable times, any factory, warehouse or establishment in which food, drugs, devices or cosmetics are manufactured, processed, packed, or held for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices or cosmetics in interstate commerce; and (2) to inspect at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed,

packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act...No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data (other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (j) or section 507 (d) or (g) of this Act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505 (j) of this Act). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness..."

(3). Defendants moved for dismissal of the "Petition as limited and amplified by Plaintiff's Bill of Particulars" on the ground, among others, that it "fails to set forth facts sufficient to constitute a criminal contempt of court" (15-18).

Judge Dooling, in a six page Memorandum and Order (19-24), ruled inter alia (emphasis added):

"1. Section 374(a) is not involved. If employees duly designated by the Secretary present appropriate credentials and a written notice to the owner, they are authorized to enter plants where devices are held for introduction into commerce or

after such introduction and to conduct the statutory inspection of the premises. Refusal to permit entry or inspection as authorized by Section 374(a) is a prohibited act (21 U.S.C. 331(f)),and is a misdemeanor, or, in some circumstances a felony (21 U.S.C. 333(a)(b)). It is not a contempt of the injunction of July 18, 1974, entered in 68 C 391. Nor is a refusal to grant access and the right to inspect pursuant to Part V(B) of the injunction of July 17, 18, 1974, a prohibited act under 21 U.S.C. 331(f) nor a misdemeanor under Section 333(a). The two rights of access and inspection are distinct and refusal to permit exercise of each of the rights has distinct and different consequences.

The bill of particulars furnished by the Government correctly points out in its first paragraph that what is involved is a violation of the injunction, and not of any statute, rule or regulation." (20-21)

.....

"4. The petition does not specify the manner in which the inspectors demonstrated their authority to the defendants....

Identification in the form of FD Forms 200A and 200B would more than satisfy the requirements of appropriate caution on defendants' part.(4) No more than this was needed, and nothing less than a clear-cut manifestation to the defendants that the inspection was under the decree would serve the needs of the occasion. The Section 374(a) notification was a confusing and wholly inappropriate intrusion if an inspection under the decree was intended....

If, as the Bill of Particulars suggests, the Government did not unequivocally seek to inspect under the decree, and if it failed to make that manifest to the defendants, it would appear that the contempts charged in the petition can not be proved." (22-24)

Accordingly, the plaintiff was directed to serve a further bill of particulars,

"directed to the questions of whether or not the in-

(4) That statement overlooks the limitations of their texts (see p. 5 supra).

vestigators were authorized to inspect under the decree and what, if any, material they proferred to defendants to establish their authority and to show that they had been directed to conduct an inspection under the decree a[illegible] bounded by its terms." (24)

(4). In its further Bill of Particulars (25-38), the Government asserted that only the "officers and employees of the Federal Food and Drug Administration who are authorized to conduct inspections and investigations" are those to whom "FD Forms 200A, B and C" had been issued and remain in force (26-27). The "investigators who attempted to conduct the inspections alleged in the petition", the Bill of Particulars said, carried and exhibited those "Forms" (28) and, in contradiction to Judge Dooling's views, argued

> "Assignment from a superior directing that a particular inspection pursuant to the injunction be conducted provides no additional authority for the investigators to conduct an inspection." (28; emphasis added)

Such assignments, the Bill continued, "were issued with respect to the attempted inspections...these assignments were not exhibited to the defendants." (28; emphasis added). The Section 374(a) Notices of Inspection (quoted at pages 6-7 supra) were issued and delivered to the defendants "at each of the attempted inspections...because Food and Drug Investigators are required to issue such a notice each time they conduct an inspection as here." (28-9; emphasis added)

Also, "At each of the attempted inspections, the

fendants were notified" -- presumably only orally, there being no claim to the contrary -- "that the inspectors were present to conduct an inspection of the premises and all records." (31; emphasis added); "a certified copy of the injunction" was not exhibited; nor was "the investigators' internal Agency assignment";(29) the defendants "were orally advised by the investigators that the authority for the attempted inspection was the Permanent Injunction"(30-31). "At the inspection of October 7, 1975" -- [but not on July 2nd and not on October 15th] -- Investigator Kurzman read to Mr. [Joseph I.] Ross pertinent portions of Section V(B) of the Injunction." (30-31)

To that Bill of Particulars were annexed some five pages of teletype communications from the "FDA Division of Compliance, Michael J. Matlock,to the New York District Office, Attn: G.J. Gerstenberg" (32-38). Three of those pages were dated "6/18/75"; two and a fraction were dated "10/3/75"; the remainder was dated "10/3/75".

Annexed to the further Bill was another communication dated "10/14/75" from "Dan R. Beardsley of the Division of Compliance" to the "New York District Office, Attn: K.N. Klein". (38)

The June 18, 1975 communication requested "an in-depth inspection of the Diapulse Corporation of America, and all its related business addresses" (32), the objective being :

"If we can establish that they are in violation of the permanent injunction, then we will be prepared to go before the court and seek redress" (33). That communication included an overstatement that the "injunction required" the Diapulse Corporation "to cause the prohibited devices to be recalled to their headquarters or other suitable facilities approved by the Food and Drug Administration"; in fact, the injunction required the Diapulse Corporation only to notify known purchasers or holders of such devices to ship them to the Diapulse Corporation and Diapulse was not required to take measures to compel such shipment. Moreover, the last paragraph of the June 18, 1975 Telex contains the statement: "Mr. Patterson (G C F - 1) agrees that references to a recall be deleted" (34; emphasis added).

The "10/3/75" communication stated: "Following a ACC/SCF/NYK-DOL BMDDP conference 10/2/75 it was decided FDA should again attempt a F/V inspection...to determine if Diapulse will permit an inspection of their premises" (35); and it set forth instructions therefor (35-37).

The "10/14/75" communication was: "We are in receipt of your TWX 10/9/75 regarding the firm's Vice President and Treasurer denying the investigators entry to the premises in order to carry out their inspection. In the absence of the President of the corporation, Jesse Ross, we con-

cur with your recommendation that an inspection be attempted upon his return" (38).

(5). Based upon that further bill of particulars as well as upon Judge Dooling's Memorandum and Order of March 31, 1976, and the previous papers, defendant again moved for a dismissal (39-45). By a Memorandum and Order, dated April 28, 1976, Judge Dooling ruled:

> "In light of the further bill of particulars filed April 13, 1976, it may be that at the trial the Government will be able to prove the charges of paragraphs 4 and 5 of the Petition. No way of proving the alleged contempt of July 2, 1975, appears from the petition, paragraph 3, and the bill of particulars filed April 13, 1976. Accordingly, only the charges with respect to the October 7 and October 15, 1975, inspections (paragraphs 4 and 5) may be tried. The charge of paragraph 3 will not be tried but is stricken as insufficient when read with the bill of particulars.
>
> It is so ORDERED."

Seemingly, the raison d'etre of that ruling was that according to the further bill of particulars, the investigators on July 2, 1975 were not sufficiently explicit in informing Mr. Jesse Ross that access and inspection were being demanded under the terms of the injunction.

The Trial

(6). At the commencement of the trial, counsel for the defendants renewed his prior motions to dismiss as they related to the two October 1975 counts (94-100). Coun-

sel stressed that under the second bill of particulars "the Government states its position to be that the F.D.A. could authorize inspection only under its own procedures and, therefore, the investigators were required to give written notice [and] that written notice...was limited to inspection under the Act" (94). Counsel repeated (at 98): "What I am questioning is whether the F.D.A. has exercised the power under [the] injunction in the manner in which they say" was mandatory, namely by written notice setting forth the scope and authority therefor. "The notice which they gave did not mention the injunction. On the contrary, its terms excluded certain portions of the injunction"(98-9).

Judge Dooling replied that he "had fully considered all of this in the earlier stages" (94), that the points which counsel was urging "are spelled out in detail in this record [and] are carefully preserved...So that the course of discretion would seem to be to conduct the trial rather than" engage in further reargument (95). Accordingly, Judge Dooling denied the motion to dismiss (99).

(7). The Government's first witness, Murray Kurzman, testified that on October 7, 1975 he was in the employ of the F.D.A. as a "special investigator" with duties "to inspect premises which manufactured or packed or held food, drugs, cosmetics and devices which were interstate commerce or received in interstate commerce" (101; emphasis added).

Prior to October 7, he had received "a teletype which was transmitted to our office from headquarters in Rockland, Maryland" (102). Upon it being offered in evidence, it was developed on voir dire that neither Mr. Kurzman nor the investigator who accompanied him presented a copy of the teletype or informed the defendants of its contents or substance (104-5). An objection to the receipt of the teletype in evidence, on the ground that neither it or its contents had been brought to the notice of defendants was overruled (106) and, over defendants' exception, the teletype was received in evidence as Government's Exhibit 1 (104). A copy of that teletype of October 3, 1975 was annexed to the further bill of particulars (35-37; cf. the two paragraphs read to the jury at 104 with 36).

On October 7, Mr. Kurzman proceeded to the premises of Diapulse Corporation with another F.D.A. agent, Harry Baukney (105-9). When Mr. Joseph I. Ross arrived, and identified himself as Vice-President and Treasurer of Diapulse (107-110), the two agents showed Mr. Ross their "credentials" and issued to him "a written notice of inspection" (110), telling Mr. Ross they "were legally obligated to do so" (111; emphasis added). Thereupon they said they "wished to inspect the physical premises" and the company's "production and sales records" of "machines known as Diapulse" and "as P/EMF"

(114).

Mr. Joseph Ross replied that he had "to defer permission" to see the records until "Mr. Jesse Ross was available...the following October 15" (112).

The agents "asked Mr. Joseph Ross if he would have any objection to our inspecting" other premises "which were used as warehouses, storage, component storage for Diapulse Corp." (113). Mr. Ross replied "that those places were not under his firm's control" (113).

Responding to questions by the investigators, Mr. Joseph Ross told them that "the Diapulse machines were being manufactured on the premises...for sale within New York State and for export" and there were in the premises records pertaining thereto as well as to P/EMF machines and P/EMF modification kits (114-15). The investigators asked other questions and made requests to see other records (115-118); Mr. Joseph Ross stated that "This would require Mr. Jesse Ross' decision" (119). Incidentally, investigator Kurzman erred if, as he testified (118), he told Mr. Joseph Ross: "There had been no provision made that the Diapulse machines would be made available for investigatory [research] purposes". In fact the injunction contained express exclusion therefrom of "shipment or other delivery for investigational or research purposes" (Section IV(C); and Mr. Joseph Ross gave the F.D.A.

investigators the serial numbers of 8 Diapulse machines which had been loaned to the University of Virginia for research purposes (118).

At that point, Mr. Kurzman took out from his folder a copy of the injunction, "turned to section V(B) and informed Mr. Ross what the actual provision is in section V(B)" (119). Prompted by the question "Did you read any portion of that section to Mr. Ross", Mr. Kurzman answered "Yes, I did" (120); at the request of the Government's counsel, Mr. Kurzman read to the court and jury that section V(B) (120; that text is reproduced at page 3 supra). Then he told Mr. Joseph Ross that he "did not see anything in here which indicated that Mr. Jesse Ross had to be present"; Mr. Joseph Ross replied that "Mr. Jesse Ross' presence was necessary" (121). At that point, both Mr. Kurzman and Mr. Baukney left the Diapulse premises (121).

It will be noted that counsel for the Government abstained from adducing the credentials which, according to the Bill of Particulars, they had exhibited and the notices which they had issued to and left with Mr. Joseph Ross. Those were adduced on cross-examination and were introduced as Defendants' Exhibits A, B and B1 (129-135). Their respective texts are reproduced at pages 4-7 supra. Neither inspector had with him any copying equipment or supplies (135-6). On his cross examination, Mr. Kurzman also acknowledged that Mr. Joseph Ross had

told him that the 8 machines that had been sent to the University of Virginia had been sent with the permission of the F.D.A. (137). Mr. Kurzman knew that they had been sent to the University and had no information that they had been returned (137).

(8). Presumably in accordance with the "10/14/75" teletype (supra pp. 11-12), Mr. Kurzman and Mr. Baukney revisited the Diapulse premises on October 15 (121-3). On that occasion, they saw both Jesse and Joseph Ross (123-4). After exhibiting their identification cards, Mr. Jesse Ross ushered the agents into a conference room and asked them whether they objected to having the session tape recorded (124). After telephoning his superiors, Mr. Kurzman reported there was no objection (124-5). On cross examination, the recording was played (139-154). Mr. Kurzman acknowledged that the tape as played was "an accurate recording of what had transpired" (146). Hence,as to what occurred on October 15, the recording supersedes whatever oral testimony was adduced.

Mr. Kurzman said to Mr. Jesse Ross: "We are presenting you as required by law [emphasis added] with a Notice of Inspection" and ask to be granted "an inspection of the premises, records and production of the Diapulse Corporation of America" (142). Thereupon Mr. Jesse Ross read aloud from the Notice of Inspection that inspection is limited to places "in which

food, drugs, devices or cosmetics are manufactured, processed, packed or held for introduction into interstate commerce" and said: "At the present time we're not manufacturing or selling or introducing anything into Interstate Commerce. So, therefore, we have nothing to show you" (142-3). Mr. Kurzman replied: "We are prepared in this case, to advise you that it is our feeling that this refusal of yours is a violation of the Food, Drug and Cosmetics Act as well as the terms of the injunction" (143). Mr. Jesse Ross countered: "I am requesting you to state how and why?" The reply was: "This is what we've been instructed to tell you. We are not prepared or in a position, personally, to advise you. We are not in a position to interpret the law or definition of Interstate Commerce" (143; emphasis added).

Mr. Joseph I. Ross then said: "As a matter of fact, I believe we are not refusing...We are simply telling you we had [have] nothing for interstate commerce. We are not refusing you an inspection. We are not refusing you anything. We have nothing to show you." (143). Again at 144: "We're not refusing inspection. You keep on saying that. It is not correct. You are asking us to show you our records concerning interstate commerce. We say we don't have anything for interstate commerce" (144; emphasis added). Thereupon Mr. Kurzman remarked it was obvious that nothing further would be gained

by further discussion and he and Mr. Baukney left (144).

The identifications which Mr. Kurzman and Mr. Baukney exhibited were those which they had exhibited on October 7 (137-8). The Notice of Inspection which they issued and delivered to Messrs. Ross was exactly the same as had been issued and delivered on October 7, save that it was dated October 15, 1975 and was addressed to "Mr. Jesse Ross, President Diapulse Corporation of America" (14, 138-9).

(9) FDA Agent Baukney, who had accompanied FDA Agent Kurzman on October 7 and October 15, then was called to the stand by the Government. Its counsel, over defendants' objection and exception, adduced a teletype from F.D.A. Headquarters which was introduced in evidence as Government's Exhibit 4 and from which the witness read extensively to the jury (154-161; cf. 32-34). A motion to strike was denied with an admonition (presumably to the jury) to disregard the contents other than as evidence of authorization of the inspection (161-2). Government's counsel then proceeded to interrogate the witness in regard to July 2, 1975 (the count that had been dismissed); objection thereto was overruled (162-5). Mr. Baukney testified that upon seeing Mr. Jesse Ross, he issued to him a Notice of Inspection and told Mr. Ross that he was here to inspect the premises under the provisions of the injunction (163-4).

Mr. Baukney corroborated Mr. Kurzman's testimony re-

garding the October 7 visit and the accuracy of the October 15 tape recording (165-8).

Defendants' counsel felt obligated to cross-examine Mr. Baukney regarding his July 2 visit. He produced the identification card which he had exhibited and it was introduced as Defendants' Exhibit D (168-9). The text thereof is reproduced at page 5 supra. The Notice of Inspection which he issued to and left with Mr. Jesse Ross was in the same form as those issued on October 7 and 15 (Defendants' Exhibit E, 169-171; the relevant portion of the text is reproduced at pages 6-7 supra). When he told Mr. Jesse Ross that "the purpose of our visit was to conduct an inspection and review records under the provision of the injunction", Mr. Ross "asked what records" and he, Baukney, responded "we would be more precise when we were completed with the Notice of Inspection". Mr. Ross stated "he has not been distributing any Diapulse devices in Interstate Commerce since the time of the injunction". Thereupon Mr. Baukney said that he wanted "to make an inspection and to review records to determine that what he, Mr. Ross, said was the case" (172). Mr. Ross replied that his attorney "was interpreting the injunction decree to mean that inspection would be permitted only if the firm was distributing the devices in interstate commerce" (172, 174) and, in substance, if F.D.A. wanted to pursue the matter they should set forth in writing what they wanted and his attorney "would respond" (172). Thereupon Mr. Baukney and his compan-

ion left (172). They did not have with them a copy of the injunction and did not read to Mr. Ross any part thereof (172).

When questioned on cross-examination regarding his October 7 visit with Mr. Kurzman, Judge Dooling commented (173):

> "At that time...it boiled down to...he deferred the inspection until such time Mr. Jesse Ross would be present."

(10). The Government then rested. Motions for dismissal of the petition and for acquittal were then made on the grounds previously urged and on the ground that the evidence failed to establish the charges beyond a reasonable doub . After a brief argument (the report of which is woefully garbled in the transcript -- pages 186-7), the motion was denied (177).

(11). Mr. Jesse Ross, the first defense witness, testified that at no time after July 18, 1974 did the Diapulse Corporation manufacture or produce anything for introduction in, or introduce in, interstate commerce (178). On July 2, 1975, he told the investigators that "we had nothing to show them" in relation to interstate commerce and also "suggested that they submit their requirements in writing so that I can submit them to our attorney' for his advice and "if there was any question we would go back to the court for a decision" (180-1).

A letter from defendants' attorney, dated August 14, 1974 was then introduced in evidence as Exhibit G (180). Mr. Ross testified that he was not a lawyer, had never studied or

been trained in law and relied on the contents of that letter and acted accordingly (181, 183).

In the course of a protracted repetitious cross-examination (185-243) Mr. Jesse Ross, responding to questions, testified that his attorney's letter advised him that he was entitled to receive "a written notice of authorization to enter described portions of the premises" and containing a specification of what is to be inspected; that, Mr. Ross said, "we never received" (197). The letter told him also: "If the credentials and notice are satisfactory tell him (198): that you do not manufacture, process, pack, or hold, and since September, 1972, have not manufactured, processed, packed or held any device in whole or in part, assembled or unassembled, or components", etc., for interstate commerce.

All of the notification and reporting requirements of the injunction judgment were complied with (186); the last of the dates specified therefor expired on or about November 15, 1974. On that day the Diapulse Corporation reported to the F.D. that to the date thereof no machines had been returned but had been informed by two trucking companies that some equipment was en route, but received no details (244).

Mr. Ross acknowledged that thereafter the Diapulse Corporation had received several machines which had been in interstate commerce (213, 214, 224). He acknowledged also that under the injunction, F.D.A. was

entitled to access to those machines (200-203, 211) upon proper written notice in writing that access was demanded under the injunction (213,214,224).

In the course of that cross-examination, the court phrased a question which the witness said he did not understand, and the court reacted: "You do understand, answer the question please, Mr. Ross, don't play", whereupon Mr. Ross said: "Would you repeat the question please, I don't understand"?

Defendant Jesse Ross had been questioned on cross-examination about refusals to admit F.D.A. agents in 1972. He was asked on redirect: "Was that followed by any application to punish you for contempt?", and the witness answered, "No sir". On objection from counsel for the Government, that answer was stricken and defendants' counsel took exception (243).

(12). Mr. Joseph I. Ross' testimony, in respect to October 7, did not materially differ from the investigators' testimony but emphasized that he had requested them "to note that [he] did not refuse them inspection...just asked them to wait until Mr. [Jesse] Ross came back" about a week hence. He testified also that he "in good faith believed absolutely" he was not violating the injunction because the "Notice of Inspection" made no reference thereto (256-7; see also 260).

(13). Called as a defense witness, an attorney in the office of the General Counsel of the Health, Education and Welfare Depar_ment, testified (at 262-3) that he had reviewed the documents which constituted Government's Exhibit 4 (35-38) which purportedly had been issued by Mr. Matlock. He did not know what position Mr. Matlock held in the F.D.A. other than that he was a "compliance officer" (270). He gave the same answer in regard to Dan R. Beardsley the purported author of the October 14, 1975 directive which was also included in Exhibit 4 (38,270).

That attorney had been an active participant in the litigation against Diapulse and was in frequent communication with the United States Attorney's office, particularly Mr. Hyman, and he knew who was representing Diapulse in that litigation (267-8). He was informed that Diapulse Corporation was refusing to allow inspection on the interstate commerce ground (266-7). Asked whether he had communicated with counsel for Diapulse directly or through Mr. Hyman, to try to arrive at a consensus, an answer was prevented by a sustained objection (269-70).

Following that testimony, both sides rested (274).

(14). Counsel for the defendants then moved for dismissal and/or a direction of acquittal on a number of grounds: 1. The absence of adequate proof of authorization by the Secretary of Health, Education and Welfare or a duly authorized

delegate of the Secretary to conduct any of the frustrated investigations; 2. The absence of written Notice of Demand of Access under the injunction; indeed the written notice which was given and the credentials which were exhibited were limited to access under section 21 U.S.C. 374(a); 4. There was no proof of intent or desire on the part of any of the defendants to disobey the injunction or a feeling or knowledge or belief that they were disobeying the injunction; 5. There was no proof justifying a finding of guilt beyond a reasonable doubt; and 6. In respect to the October 7 charge, the additional ground that there was no refusal that day but rather a postponement (277-279).

The motion was denied and exception was taken thereto (279,282).

(15). In the course of the discussion which followed of the court's proposed charge, defendants' counsel requested a charge that written notice of demand of inspection under the injunction as distinguished from inspection under 21 U.S.C. 374a, was prerequisite (291; the attribution of that request to Mr. Hyman is an error). The court declined to so charge and defendants' counsel took exception (291).

THE PERTINENT STATUTES

The Government's Bill of Particulars specified that it relied on 18 U.S.C. 401 and rule 42b of the Federal Rules

of Criminal Procedure.

Section 401 reads as follows:

"§401. Power of court

A court of the United States shall have power to punish by fine or imprisonment, at its discretion, such contempt of its authority, and none other, as --

(1) Misbehavior of any person in its presence or so near thereto as to obstruct the administration of justice;

(2) Misbehavior of any of its officers in their official transactions;

(3) Disobedience or resistance to its lawful writ, process, order, rule, decree, or command. June 25, 1948, c. 645, 62 Stat. 701."

The pertinent provisions of the Federal Food, Drug and Cosmetic Act section 704(a), 21 U.S.C. 374(a) are reproduced at pages 6-7 supra.

I

NEITHER ON OCTOBER 7, 1975 NOR OCTOBER 15, 1975 NOR JULY 2, 1975 WAS ACCESS DEMANDED UNDER THE INJUNCTION BY A "DULY AUTHORIZED" OFFICER OR EMPLOYEE OF THE FOOD AND DRUG ADMINISTRATION.

Obviously, access need not be given to anyone who does not establish that he is "duly authorized". The Government's Bill of Particulars averred that inspections may be conducted by only such of its officers and employees to whom "FDA official credentials" have been issued in accordance with

21 CFR 2.121 (p) (3) (10). "The credentials", the Bill of Particulars says,"were exhibited by the investigators at the time of the attempted inspections" (10). In addition, "a document entitled 'Notice of Inspection'was presented" (10).

In its Supplemental Bill of Particulars, the Government added: "It is only those employees who have been specifically designated or who are authorized to conduct inspections for the Food and Drug Administration. The credentials carried by the investigators...were exhibited by them at the time of the attempted inspections" (27). They also, on each occasion "issued to the defendants" a Notice of Inspection. "Such notices were issued because Food and Drug Administration Investigators are required to issue such a notice each time they conduct an inspection as here, for the enforcement of the Federal Food, Drug and Cosmetic Act."

The Government's Supplemental Bill of Particulars theorizes that: "Since the investigators at each inspection exhibited the credentials..., the defendants were required by section V(B) of the injunction to allow the inspection of the premises and records to be conducted" (29).

The Government's Supplemental Bill of Particulars also argues that the investigators were not required and did not exhibit a copy of the injunction, since it contained no such requirement and "Similarly, a copy of the investigator's internal

Agency assignment was not exhibited to the defendants, since the injunction does not provide therefor"(28).

That illogic is compounded by the further averrment: "Such notices were issued because Food and Drug Administration investigators are required to issue such a notice each time they conduct an inspection as here, for the enforcement of the Federal Food, Drug and Cosmetic Act" (28-9; emphasis added).

The Supplemental Bill of Particulars studiously avoids referring to the texts of the identifications and of the notices.

Those texts are reproduced at pages 5-7 supra. Each of the documents specifies that the authority of the investigators is limited to inspections authorized by the act and only to the extent and in the circumstances specified in the quoted section of the statute.

On the one hand, the FDA asserts that the notice was necessary to establish the authority of the investigators and, on the other hand, those limitations were nullified by the oral assertion of the investigators that they were seeking access also under the Permanent Injunction, and it was wholly unnecessary to offer any authenticated written evidence that they were duly authorized to demand access under the terms of the injunction. Their mere unsupported assertion, the Government argues, was sufficient to compel the defendants to disregard the limitations of their duly authticated credentials and the formal printed notices.

Judge Dooling clearly perceived the incongruity of

the Government's position. The statute, he said, "is not involved". Violation of the statute, he said further, was "not a contempt of the injunction". Invocation of "section 374(a)", he said, "was a confusing and wholly inappropriate intrusion" and "nothing less than a clear cut manifestation to the defendants that the inspection was under the decree would serve the needs of the occasion" (see pages 7-8 supra).

Surely, authority is not established by an oral negation of presented documents.

In a civil action, would authority be held to be established by an oral contradiction of contemporaneous submission of official documentation? All the more curious and strange, is a conviction that a criminal contempt was committed by the refusal to accept a totally unsupported oral assertion of authority in contradiction of the Government documents which the Government asserts were indispensably submitted to demonstrate the authority of the investigators.

It follows from the foregoing that:

1. The Petition as amplified by the Bills of Particulars not only failed to set forth facts sufficient to constitute the charged contempts; the allegations established affirmatively that there was no violation of the injunction.

2. Not only did the evidence fail to establish contempt; the evidence affirmatively established the absence thereof.

3. Hence, it is unnecessary to press the more obvious point that surely the evidence failed to establish guilt beyond a reasonable doubt, as required by Gompers v. Bucks Stove & Range Co., 221 U.S. at p. 444; Parker v. United States, 153 F 2d 65, 70 (1st Circ., 1946); In Re Brown, 454 F 2d 999, 1007 (C.A., D.C. Circ., 1971): "Knowledge that one's act is wrongful and a purpose to nevertheless do the act are prerequisite to a criminal contempt" (id).

4. It is unnecessary also to stress the additional vulnerability of the conviction of Joseph I. Ross of the October 7 charge (see pp. 14-17, 21, 23).

5. Nor is it necessary to argue the errors implicit in the first paragraph on page 14 supra, in paragraph (9) supra page 19, in the first and second paragraphs on page 23, in paragraph (14) supra pages 24-25 and in paragraph (15) supra page 25.

6. It is unnecessary to elaborate the point

that even if guilt were established, the fines were excessive. In this connection, it is noteworthy that coordinate section 402 of 18 U.S.C. puts a top limit of $1000 as a fine upon a natural person convicted of a contempt which is "also a criminal offense under any statute..."

II

EACH OF THE CONVICTIONS SHOULD BE REVERSED AND THE PETITION SHOULD BE DISMISSED.

Respectfully submitted

COPAL MINTZ
Attorney for Defendants-Appellants

Dated: October 14, 1976.

ADDENDUM

For completeness, the following documentation is added: The jury found Jesse Ross guilty of the October 15 count, Joseph I. Ross guilty of both the October 7 and 15 counts (339-341) and the guilt of the corporation on both counts followed as a matter of course (294). Defendants made a timely motion for the setting aside of the verdict (50-56). It was denied (57). Sentence was pronounced on August 27, 1976 (90-92): The corporation was fined $2500, Mr. Joseph I. Ross was fined $625 on each count making a total of $1250 and Mr. Jesse Ross was fined ~~$1250~~ $2500 on the October 15 ~~each~~ count ~~making in all $2500~~ (id).